

U.S. Food and Drug Administration

Manufactured Food Regulatory Program Standards

OMB Control No. 0910-0601

SUPPORTING STATEMENT A. Justification

1. Circumstances Making the Collection of Information Necessary

The FDA is requesting approval from the Office of Management and Budget (OMB) for information collection contained in the program standards. These collections are being performed to determine and develop inspection programs when jurisdiction overlaps between FDA and State agencies. The Secretary is authorized under the FDA Food Safety Modernization Act (Pub. L. 111-353) to collect and share information with the States.

2. Purpose and Use of the Information Collection

FDA collects information via self-assessment worksheets that are completed by state food regulatory agencies. The purpose of the information collection is to perform a validation audit and evaluate state conformance with the Manufactured Food Regulatory Program Standards (MFRPS). This information collection will be used by both FDA and the States to maximize the use of resources and better direct their regulatory activities at reducing foodborne illness hazards in firms that manufacture, process, pack, or hold foods.

The validation audit should occur within 18 months. A subsequent validation audit will be conducted at 36 months to evaluate the State's progress toward fully implementing the standards. Then, at 60 months, FDA will conduct a comprehensive program audit. As part of the program audit, the auditor reviews the records and supporting documents required by the criteria in each standard to determine if the self-assessment and improvement plan accurately reflect the State program's level of conformance with each of the standards.

3. Use of Improved Information Technology and Burden Reduction

FDA estimates that 98 percent of the respondents will use electronic means to fulfill the agency's requirement or request. Current practices allow the reporting and recordkeeping requirements to be met through electronic means. The fill-in forms and worksheets will be in Portable Document Format (PDF), Excel or Word Format and available on the internet.

4. Efforts to Identify Duplication and Similar Information

The information described is not duplicative and must be obtained from the States.

5. Impact on Small Business or Other Small Entities

FDA does not anticipate responses from small businesses and does not believe it will adversely affect small businesses or other small entities. The Manufactured Food Standards do not impact business or small entities.

6. Consequences of Collecting the Information Less Frequently

Collecting the information solicited in this collection less frequently would negatively impact FDA's ability to evaluate annual grantee performance. The twice annual collection is proportionate and appropriate.

There are no technical or legal obstacles to the collection of this information.

7. Consistency with the Guidelines in 5 CFR 1320.5

There are no special circumstances for this collection of this information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of 4/17/2019 (84 FR 16020) to which the agency received no comments.

9. Explanation of any Payment of Gift to Respondents

No gift or payment is offered to respondents for completing the information collection. The standards do correspond to a grant program that conforms to federal regulations.

States can apply for a cooperative agreement allowing them to receive up to \$300,000 each year for a period of five years to work toward significant conformance with the ten standards. The States will conduct a baseline self-assessment and develop a strategic plan to fully implement the program standard in five years. States will be applying for additional funds for continual improvement and enhancement projects for the next awarded cooperative agreement being offered to support the enrollment of the MFRPS.

10. Assurance of Confidentiality Provided to Respondents

This ICR is not collecting personally identifiable information (PII) or other data of a personal nature. Information collected is about state food safety programs through the Manufactured Food Regulatory Program Standards which ranges from information about state laws and regulations to procedures for dealing with foodborne illness outbreaks.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected. FDA determined that PII is not collected, and the Privacy Act does not apply to this collection.

11. Justification of Sensitive Questions

This information collection does not include questions pertaining to sexual behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

The total estimated annual reporting burden for implementation is 569 hours per respondent for a total of 24,467 (43 x 569). The burden was determined by capturing the average amount of time for each respondent to assess the current state of the program and work toward implementation of each of the ten standards contained in the MFRPS. The hours per respondent will average the same to account for continual improvement and self-sufficiency in the program.

FDA estimates the burden of this collection of information as follows:

Respondent	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
State Departments of Agriculture or Health	43	1	43	569	24,467

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

The recordkeeping burden associated with documenting conformance to the program standards average to 40 hours per record.

Respondent	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Record-keeping	Total Hours
State Departments of Agriculture or Health	43	10	430	40	17,200

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

13. Estimate of the Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this collection of information.

14. Annualized Cost to the Federal Government

The information collection itself will not incur any annualized cost to the federal government.

15. Explanation for Program Changes or Adjustments

This extension request is a revision (program change). One additional State has enrolled in the program since 2016. The total estimated burden for this collection has increased by 25,875 hours to 41,667 hours among 43 respondents, from a previous total of 15,792 hours among 42 respondents. This increase is due to a change in the self-reported response times provided by the respondents, the addition of the State in 2016, and the addition of estimated recordkeeping burden for this collection. Because this is a long-term program, we believe these changes are the result of more precise documentation by participating agencies as they have grown more experienced over time.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish the results of this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Not applicable.

18. Exception to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.